Technical Information Report

AAMI TIR30:2011

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A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

Association for the Advancement
of Medical Instrumentation

AAMI Technical Information Report

AAMI TIR30:2011
(Revision of AAMI TIR30:2003)

A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

Approved 10 August 2011 by
Association for the Advancement of Medical Instrumentation

Abstract: This report is intended as a resource for manufacturers of medical devices who must validate the instructions for reprocessing that they include with their devices. In addition to describing available processes, materials, test methods, and acceptance criteria for cleaning medical devices that are labeled by the manufacturer for reuse and reprocessing, the report also discusses some of the underlying problems and challenges associated with validating a cleaning method. Extensive references and a sample cleaning validation outline and also are included.

Keywords: device design, materials compatibility, test soil

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation. The code in the US column, "(R)20xx" indicates the year the document was officially reaffirmed by AAMI. E.g., ANSI/AAMI/ISO 10993-4:2002/(R)2009 indicates that 10993-4, originally approved and published in 2002, was reaffirmed without change in 2009.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

International designation	U.S. designation	Equivalency
IEC 60601-1:2005 Technical Corrigendum 1 and 2	ANSI/AAMI ES60601-1:2005 and ANSI/AAMI ES60601-1:2005/A2:2010 ANSI/AAMI ES60601-1:2005/C1:2009 (amdt)	Major technical variations C1 Identical to Corrigendum 1 & 2
IEC 60601-1-2:2007	ANSI/AAMI/IEC 60601-1-2:2007	Identical
IEC 60601-2-2:2009	ANSI/AAMI/IEC 60601-2-2:2009	Identical
IEC 60601-2-4:2010	ANSI/AAMI/IEC 60601-2-4:2010	Identical
IEC 60601-2-16:2008	ANSI/AAMI/IEC 60601-2-16:2008	Identical
IEC 60601-2-19:2009	ANSI/AAMI/IEC 60601-2-19:2009	Identical
IEC 60601-2-20:2009	ANSI/AAMI/IEC 60601-2-20:2009	Identical
IEC 60601-2-21:2009	ANSI/AAMI/IEC 60601-2-21:2009	Identical
IEC 60601-2-24:1998	ANSI/AAMI ID26:2004/(R)2009	Major technical variations
IEC 60601-2-27:2011	ANSI/AAMI/IEC 60601-2-27:2011	Identical
IEC 60601-2-47:2001	ANSI/AAMI EC38:2007	Major technical variations
IEC 60601-2-50:2009	ANSI/AAMI/IEC 60601-2-50:2009	Identical
IEC 80001-1:2010	ANSI/AAMI/IEC 80001-1:2010	Identical
IEC 80601-2-30:2009 and Technical Corrigendum 1	ANSI/AAMI/IEC 80601-2-30:2009 and ANSI/AAMI/IEC 80601-2-30:2009/ C1:2009 (amdt) – consolidated text	Identical (with inclusion) C1 Identical to Corrigendum 1
IEC 80601-2-58:2008	ANSI/AAMI/IEC 80601-2-58:2008	Identical
IEC/TR 60878:2009	ANSI/AAMI/IEC TIR60878:2003	Identical
IEC/TR 62296:2009	ANSI/AAMI/IEC TIR62296:2009	Identical
IEC 62304:2006	ANSI/AAMI/IEC 62304:2006	Identical
IEC/TR 62348:2006	ANSI/AAMI/IEC TIR62348:2006	Identical
IEC/TR 62354:2009	ANSI/AAMI/IEC TIR62354:2009	Identical
IEC 62366:2007	ANSI/AAMI/IEC 62366:2007	Identical
IEC/TR 80002-1:2009	ANSI/IEC/TR 80002-1:2009	Identical
ISO 5840:2005	ANSI/AAMI/ISO 5840:2005/(R)2010	Identical
ISO 7198:1998	ANSI/AAMI/ISO 7198:1998/2001/(R)2010	Identical
ISO 7199:2009	ANSI/AAMI/ISO 7199:2009	Identical
ISO 8637:2010	ANSI/AAMI/ISO 8637:2010	Identical
ISO 8638:2010	ANSI/AAMI/ISO 8638:2010	Identical
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-1:2009	Identical
ISO 10993-2:2006	ANSI/AAMI/ISO 10993-2:2006/(R)2010	Identical
ISO 10993-3:2003	ANSI/AAMI/ISO 10993-3:2003/(R)2009	Identical
ISO 10993-4:2002 and Amendment 1:2006	ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009	Identical
ISO 10993-5:2009	ANSI/AAMI/ISO 10993-5:2009	Identical
ISO 10993-6:2007	ANSI/AAMI/ISO 10993-6:2007/(R)2010	Identical
ISO 10993-7:2008	ANSI/AAMI/ISO 10993-7:2008	Identical
ISO 10993-9:2009	ANSI/AAMI/ISO 10993-9:2009	Identical
ISO 10993-10:2010	ANSI/AAMI/ISO 10993-10:2010	Identical
ISO 10993-11:2006	ANSI/AAMI/ISO 10993-11:2006/(R)2010	Identical
ISO 10993-12:2007	ANSI/AAMI/ISO 10993-12:2007	Identical
ISO 10993-13:2010	ANSI/AAMI/ISO 10993-13:2010	Identical
ISO 10993-14:2001	ANSI/AAMI/ISO 10993-14:2001/(R)2006	Identical
ISO 10993-15:2000	ANSI/AAMI/ISO 10993-15:2000/(R)2006	Identical
ISO 10993-16:2010	ANSI/AAMI/ISO 10993-16:2010	Identical
ISO 10993-17:2002	ANSI/AAMI/ISO 10993-17:2002/(R)2008	Identical
ISO 10993-18:2005	ANSI/AAMI BE83:2006	Major technical variations
ISO/TS 10993-19:2006	ANSI/AAMI/ISO TIR10993-19:2006	Identical
ISO/TS 10993-20:2006	ANSI/AAMI/ISO TIR10993-20:2006	Identical
ISO 11135-1:2007	ANSI/AAMI/ISO 11135-1:2007	Identical
ISO/TS 11135-2:2008	ANSI/AAMI/ISO TIR11135-2:2008	Identical

International designation	U.S. designation	Equivalency
ISO 11137-1:2006	ANSI/AAMI/ISO 11137-1:2006/(R)2010	Identical
ISO 11137-2:2006 (2006-08-01 corrected)	ANSI/AAMI/ISO 11137-2:2006	Identical
ISO 11137-3:2006	ANSI/AAMI/ISO 11137-3:2006/(R)2010	Identical
ISO 11138-1:2006	ANSI/AAMI/ISO 11138-1:2006/(R)2010	Identical
ISO 11138-2:2006	ANSI/AAMI/ISO 11138-2:2006/(R)2010	Identical
ISO 11138-3:2006	ANSI/AAMI/ISO 11138-3:2006/(R)2010	Identical
ISO 11138-4:2006	ANSI/AAMI/ISO 11138-4:2006/(R)2010	Identical
ISO 11138-5:2006	ANSI/AAMI/ISO 11138-5:2006/(R)2010	Identical
ISO/TS 11139:2006	ANSI/AAMI/ISO 11139:2006	Identical
ISO 11140-1:2005	ANSI/AAMI/ISO 11140-1:2005/(R)2010	Identical
ISO 11140-3:2007	ANSI/AAMI/ISO 11140-3:2007	Identical
ISO 11140-4:2007	ANSI/AAMI/ISO 11140-4:2007	Identical
ISO 11140-5:2007	ANSI/AAMI/ISO 11140-5:2007	Identical
ISO 11607-1:2006	ANSI/AAMI/ISO 11607-1:2006/(R)2010	Identical
ISO 11607-2:2006	ANSI/AAMI/ISO 11607-2:2006/(R)2010	Identical
ISO 11663:2009	ANSI/AAMI/ISO 11633:2009	Identical
ISO 11737-1:2006	ANSI/AAMI/ISO 11737-1:2006	Identical
ISO 11737-2:2009	ANSI/AAMI/ISO 11737-2:2009	Identical
ISO/TS 12417:2011	ANSI/AAMI/ISO TIR12417:2011	Identical
ISO 13408-1:2008	ANSI/AAMI/ISO 13408-1:2008	Identical
ISO 13408-2:2003	ANSI/AAMI/ISO 13408-2:2003	Identical
ISO 13408-3:2006	ANSI/AAMI/ISO 13408-3:2006	Identical
ISO 13408-4:2005	ANSI/AAMI/ISO 13408-4:2005	Identical
ISO 13408-5:2006	ANSI/AAMI/ISO 13408-5:2006	Identical
ISO 13408-6:2006	ANSI/AAMI/ISO 13408-6:2006	Identical
ISO 13485:2003	ANSI/AAMI/ISO 13485:2003/(R)2009	Identical
ISO 13958:2009	ANSI/AAMI/ISO 13958:2009	Identical
ISO 13959:2009	ANSI/AAMI/ISO 13959:2009	Identical
ISO 14155:2011	ANSI/AAMI/ISO 14155:2011	Identical
ISO 14160:1998	ANSI/AAMI/ISO 14160:1998/(R)2008	Identical
ISO 14161:2009	ANSI/AAMI/ISO 14161:2009	Identical
ISO 14708-3:2008	ANSI/AAMI/ISO 14708-3:2008	Identical
ISO 14708-4:2008	ANSI/AAMI/ISO 14708-4:2008	Identical
ISO 14708-5:2010	ANSI/AAMI /ISO 14708-5:2010	Identical
ISO 14937:2009	ANSI/AAMI/ISO 14937:2009	Identical
ISO/TR 14969:2004	ANSI/AAMI/ISO TIR14969:2004	Identical
ISO 14971:2007	ANSI/AAMI/ISO 14971:2007/(R)2010	Identical
ISO 15223-1:2007 and A1:2008	ANSI/AAMI/ISO 15223-1:2007 and A1:2008	Identical
ISO 15223-2:2010	ANSI/AAMI/ISO 15223-2:2010	Identical
ISO 15225:2010	ANSI/AAMI/ISO 15225:2010	Identical
ISO 15674:2009	ANSI/AAMI/ISO 15674:2009	Identical
ISO 15675:2009	ANSI/AAMI/ISO 15675:2009	Identical
ISO 15882:2008	ANSI/AAMI/ISO 15882:2008	Identical
ISO 15883-1:2006	ANSI/AAMI ST15883-1:2009	Major technical variations
ISO/TR 16142:2006	ANSI/AAMI/ISO TIR16142:2005	Identical
ISO 17664:2004	ANSI/AAMI ST81:2004	Major technical variations
ISO 17665-1:2006	ANSI/AAMI/ISO 17665-1:2006	Identical (with inclusions)
ISO/TS 17665-2:2009	ANSI/AAMI/ISO TIR17665-2:2009	Identical
ISO 18472:2006	ANSI/AAMI/ISO 18472:2006/(R)2010	Identical
ISO/TS 19218-1:2011	ANSI/AAMI/ISO TIR19218:2011	Identical
ISO 20857:2010	ANSI/AAMI/ISO 20857:2010	Identical
ISO 22442-1:2007	ANSI/AAMI/ISO 22442-1:2007	Identical
ISO 22442-2:2007	ANSI/AAMI/ISO 22442-2:2007	Identical
ISO 22442-3:2007	ANSI/AAMI/ISO 22442-3:2007	Identical
ISO/TR 22442-4:2010	ANSI/AAMI/ISO TIR22442-4:2010	Identical
ISO 23500:2011	ANSI/AAMI/ISO 23500:2011	Identical
ISO 25539-1:2003 and A1:2005	ANSI/AAMI/ISO 25539-1:2003/(R)2009 and A1:2005/(R)2009	Identical
ISO 25539-2:2008	ANSI/AAMI/ISO 25539-2:2008	Identical
ISO 26722:2009	ANSI/AAMI/ISO 26722:2009	Identical
ISO 27186:2010	ANSI/AAMI/ISO 27186:2010	Identical
ISO 80369-1:2010	ANSI/AAMI/ISO 80369-1:2010	Identical
ISO 81060-1:2007	ANSI/AAMI/ISO 81060-1:2007	Identical
ISO 81060-2:2009	ANSI/AAMI/ISO 81060-2:2009	Identical

Committee representation

Association for the Advancement of Medical Instrumentation

Cleaning of Reusable Medical Devices Working Group

This technical information report was developed by the AAMI Cleaning of Reusable Medical Devices Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the TIR does not necessarily mean that all working group members voted for its approval.

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NOTE—Participation by federal agency representatives in the development of this technical information report does not constitute endorsement by the federal government or any of its agencies.

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Foreword

This technical information report (TIR) was developed by the AAMI Cleaning of Reusable Medical Devices Working Group under the auspices of the AAMI Sterilization Standards Committee.

Manufacturers of reusable medical devices must provide validated cleaning instructions with their products in order to comply with U.S. Food and Drug Administration (FDA) regulations and, more importantly, to ensure that their products can be properly cleaned and sterilized in health care facilities and other facilities that reprocess medical devices.

The objective of this TIR is to provide to medical device manufacturers information on the cleaning agents and methods available in health care facilities and other facilities that reprocess medical devices, and to review the published literature on test soils, test methods, and acceptance criteria that can be used in validating cleaning instructions for reusable medical devices.

This document is the second edition of AAMI TIR30. A fundamental problem that exists with the creation of any document of this type is its relevancy and utility after it has been published. The development of a new class of medical device or cleaning agent or the emergence of an extremely hardy pathogen could cause enough of a change to invalidate cleaning processes that previously had been used with acceptable results. To address this problem, an attempt has been made to systematically define and categorize the underlying problems and challenges that cleaning processes, test soils, and test methods must overcome to yield a validated cleaning process. This updated version of the TIR also includes a new flow chart on cleaning validation protocols.

At least two underlying problems prompted the creation of this document. The first is a significant increase in the complexity of the medical devices being manufactured today, with the result that they have become considerably harder to clean. Generally, the complexity of validated cleaning procedures will be proportional to the complexity of the medical devices for which they are designed. Second, new pathogens (e.g., hepatitis C, antibiotic-resistant microorganisms) continue to emerge.

As used within the context of this document, "should" indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. "May" is used to indicate that a course of action is permissible within the limits of the technical information report. "Can" is used as a statement of possibility and capability. Finally, "must" is used only to describe "unavoidable" situations, including those mandated by government regulation.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Dr., Ste. 301, Arlington, VA 22203.

NOTE—This foreword does not contain provisions of the revised AAMI Technical Information Report, *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices* (AAMI TIR30:2011), but it does provide important information about the development and intended use of the document.

Introduction

Medical devices, as defined by the U.S. Food, Drug, and Cosmetic Act (21 USC 301); the Medical Device Amendments of May 28, 1976; and subsequent amendments—and as regulated by the U.S. Food and Drug Administration (FDA)—range from simple wooden tongue-depressing blades to complex and sophisticated electronic equipment such as magnetic resonance imaging (MRI) and proton emission tomographic (PET) equipment. Devices can be applied to the surface of the body or be inserted into an orifice; through the skin; or into the tissues, spaces, or organs of the bodies of humans or animals by ingestion, inhalation, skin absorption, or implantation. Devices can contact blood, mucosal tissue, muscle or other connective tissue, adipose tissue, bone, teeth, and other tissues, and they might remain in contact for short time periods or for up to a lifetime. Devices are used for a wide range of diagnostic and therapeutic applications within the medical, dental, and veterinary fields, including a variety of surgical and life-saving applications. Devices are also used to administer various medicines, drugs, vaccines, biologicals, and nutritional supplements.

Manufacturers of reusable medical devices must provide instructions on how to reprocess their devices between patient uses. Three types of risks are associated with the reuse of a medical device: (a) the risk of disease transmission from one patient to another or from environmental sources to a patient; (b) the risk of inadequate or unacceptable device performance following reprocessing; and (c) the risk of occupational exposure to bloodborne pathogens and other potentially infectious materials. Reprocessing involves several steps, including cleaning, testing for device performance, disinfection, and/or sterilization.

Cleaning a device is the critical first step in reprocessing any device after it has been used on a patient (Basile, 2008; Bayes, 2008; Darbord, 2004; Martiny et al., 2004). Failure to remove foreign material (e.g., soil, lubricants, microorganisms, organic and inorganic materials) from both the outside and the inside of the device can interfere with the effectiveness of subsequent disinfection and/or sterilization (AAMI TIR12; Chartier et al., 2001; Chu and Favero, 2000; Miles, 1991; Rutala and Weber, 1999a; Rutala and Weber, 1999b). Contamination of a variety of reusable devices and instruments (e.g., surgical instruments, ophthalmic instruments, laryngeal mask airways, endoscopes) are causes of concern for patient safety from cross-contamination between patients (Beilenhoff et al., 2008; Heeg, 2004; CDC, 2008). Cleaning is normally accomplished by manual wiping, brushing, or flushing or by using mechanical aids (e.g., ultrasonic cleaners, washer–decontaminators, washer–sterilizers) in conjunction with water and detergents to remove foreign material.

In the past, a device was considered “clean” if the person who was performing the cleaning task observed no visible foreign material. Today, however, more devices have long or narrow opaque lumens, crevices, hinges, acute angles, serrated edges, junctions between insulating sheaths, coils, or other designs that make it difficult or impossible to rely on the traditional visual endpoint. In addition, visual observation might not be adequately sensitive to detect levels of soil that could interfere with subsequent reprocessing.

There are few tests that can be used to verify cleaning. To verify cleaning of a given device, one must have a test soil and a quantitative test method for detecting residual soil after cleaning. If cleaning protocols that could be used for verification were in wide use today, they could help ensure that adequate cleaning is accomplished so that a device can be reliably disinfected and/or sterilized before it is used on the next patient.

The manufacturer must validate the instructions for reprocessing a reusable device before marketing it. In addition, manufacturers must consider

a) that exposure to chemicals, such as cleaning agents, could alter the material used in the device;

b) whether the materials of construction will absorb or adsorb chemical agents, which could then gradually leach from the material over time;

c) how cleaning processes could affect the function of the device; and

d) that cleaning processes and tools must be able to contact all areas of the device that could become contaminated.

This compendium of processes, materials, and test methods for cleaning reusable medical devices is meant to provide device manufacturers with information to facilitate the validation of cleaning processes to be used for their reusable medical devices.

A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices

1 Scope

1.1 General

This technical information report (TIR) is a compilation of available information regarding test protocols, materials, test soils, and acceptance criteria that can be used by medical device manufacturers to validate cleaning processes for reusable medical devices.

1.2 Inclusions

This TIR covers the validation of cleaning processes for medical devices that are intended and labeled by the manufacturer for reprocessing and reuse. Such devices include those that are intended for routine reprocessing and reuse (e.g., surgical instruments) and certain implant accessories (e.g., orthopedic screws) that are provided as parts of sets and that are intended and labeled by the manufacturer for reprocessing if not used during a particular procedure.

The scope of this TIR Includes the following topics:

a) Device design and material considerations

b) Available cleaning processes

c) Test soils

d) Test methods

e) Test equipment

f) Acceptance criteria

g) Regulatory considerations

This TIR also provides numerous literature references and a sample cleaning validation outline.

1.3 Exclusions

This TIR does not cover the performance of procedures for cleaning reusable medical devices in health care facilities (see ANSI/AAMI ST79), nor does it cover procedures for reprocessing single-use medical devices and hemodialyzers in health care facilities (see FDA, 2000b; and ANSI/AAMI RD47).

The test protocols, test soils, and acceptance criteria described in this TIR do not necessarily apply to the validation of cleaning processes for medical devices contaminated with prions, such as the prion that causes Creutzfeldt-Jakob disease (CJD); such devices could require specialized processing steps. For information regarding the decontamination of devices exposed to prions, see ANSI/AAMI ST79, AORN (2011a), Favero and Bond (2001), and Rutala and Weber (2010), as well as the recommendations of the Centers for Disease Control and Prevention (http://www.cdc.gov/ncidod/dvrd/cjd/qa_cjd_infection_control.htm#reprocessed).